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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,789	06/23/2006	Philippe Teissier	033339/313045	1481

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EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1781	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,789	TEISSIER, PHILIPPE	
	Examiner	Art Unit	
	HAMID R. BADR	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-12 and 16-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-12 and 16-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/18/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 11/18/2009 is acknowledged.

Claims 1, 3-5, 7-12 and 16-22 are being considered on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the microorganism(s) is/are essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism(s) is/are not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit(s) of the microorganism(s). The specification does not disclose a repeatable process to obtain the microorganism(s) and it is not clear from the specification or record that the microorganism(s) is/are readily available to the public.

This rejection may be overcome by establishing that the each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein.

If the depository is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his/her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney over his/her registration number, showing that,

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

(d) the deposit will be replaced if it should ever become inviable.

The specification must also state the date of deposit(s), the number(s) granted the deposit(s) by the depository and the name and address of the depository.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

3. Claims 2-3, 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 2-3, 21-22 are indefinite for “the granules of lactic acid bacteria particles". It is not clear what is meant by this phrase. Since granules are expected to be particles, it is not clear what is meant by this phrase.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rutherford et al. (US 5,292,657; hereinafter R1) in view of Shin et al. (US 6,447,823; hereinafter R2) and Van Hoey-De-Boer et al. (EP 0940784; hereinafter R3)

7. R1 discloses a process for preparing microspheres of freeze-dried microorganisms coated with fatty material.

8. R1 discloses a fatty matrix such as stearic acid having a melting point of 40—75C. (Col. 2 line 62- Col. 3, line3). Given that stearic acid is disclosed by R1, fatty acids as presently claimed, would be obvious.

9. R1 discloses that bacteria such as Lactobacilli, and Bacillus can be used in the process (Col. 3, lines 13-16).

10. R1 discloses that the particles (granules) contain 50%-over 90% by weight of the fatty component. (Col. 3, lines 21-23).

11. R1 discloses the particle size range of 75-300 microns with the preferred range being less than 250 microns. (Col. 4, lines 7-9). Granules of less than 200 micron as presently claimed , are then obvious over R1.

12. Given that R1 discloses the use of freeze-dried (lyophilized) bacteria, the use of a lyoprotectant is inherent in the process of freeze-drying. The particle size of the bacteria and the water activity of the freeze-dried culture are also inherent in the freeze-dried bacterial culture.

13. Given that the matrix is a fatty material containing freeze-dried bacteria, it is clear that the microshperes containing bacteria will be free of starch as presently claimed.

14. Given that a freeze-dried culture is used in the process by R1, the number of dormant organisms in the dehydrated culture will depend on the initial number of those organisms in the culture broth before freeze-drying. It is noted that the total number of the dehydrated organisms in freeze-dried (lyophilized) samples are usually 10^8-10^12 CFU/g, therefore, the bacterial count per gram of the product as presently claimed is obvious.

15. While R1 gives the details of preparing microspheres of bacteria, R1 is silent regarding the Lactobacilli and Bifidobacteria strains as presently claimed. R1 is also silent regarding the incorporation of microspheres into fermented milk products or fruit or vegetable juices.

16. R3 discloses a probiotic nutritional preparation comprising 10^6 to 10^14 viable cells per gram of the preparation including Bifidobacteria, Enterococcus and Lactobacilli. (Abstract). R3 discloses that the preparation can be in the form of a food supplement, a ready-to-use food composition or infant formula. (Abstract).

17. R3 is silent regarding the incorporation of these probiotics in liquid foods.

18. R2 discloses the incorporation of encapsulated lactic acid bacteria into yogurt wherein the encapsulated lactic acid bacteria are uniformly distributed in the liquid yogurt. (Abstract)

19. R1 discloses that the incorporation of encapsulated lactic acid bacteria into yogurt will protect the bacteria so that during the passage of these bacteria through the gastrointestinal tract, the gastric acid will not kill them.

20. R2 discloses the Lactobacillus, Leuconostoc, Pediococcus, Streptococcus and other lactic acid bacterial can be encapsulated and incorporated into the yogurt product. Given that R1 discloses the encapsulation and incorporation of lactic acid bacteria into yogurt, it is obvious that such bacteria can include the lactic acid bacteria as presently claimed.

21. R2 also disclose the specific gravity concept and teaches of using encapsulated materials having a specific gravity similar to that of yogurt so that a uniform distribution of particles in the yogurt be achieved. Given that R1 discloses the uniformity of the product based on the specific gravity of the encapsulated material and the yogurt, specific gravities of encapsulated lactic acid bacteria can be manipulated to make them compatible with products containing any concentration of water including the water

contents as presently claimed. Depending on the total number of organisms in the encapsulated material, the level at which such encapsulations are incorporated into products can also be manipulated. The amount of encapsulated material is therefore determined by the desired level of microorganisms in the finished product.

22. Given that the incorporation of encapsulated organisms into yogurt is disclosed by R1, the pH and the water content of the product (yogurt) will be in the same range as presently claimed.

23. R1 clearly discloses the preparation of coated (encapsulated) lactic acid bacteria in a matrix which does not contain starch. Additionally the coated bacterial particles have a 75-300 micron range. R2 incorporates encapsulated lactic acid bacterial materials into a liquid yogurt in order to protect such bacteria during their passage through the intestinal tract. Therefore, it would have been obvious to one of ordinary skill in the art to coat (encapsulate) lactic acid bacteria as taught by R1 and incorporate them into food products as taught by R2. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in making the coated particles and using them in foods.

Response to Arguments

Applicants' arguments have been thoroughly reviewed. These arguments are not deemed persuasive for the following reasons.

1. Applicants argue that Lactobacillus casei I-1518 was deposited under Budapest Treaty and attach a certificate of deposit to that effect.

a. A careful review of the attached document reveals no identity of the microorganism. The name “Lactobacillus casei” in not mentioned in this certificate. Therefore, verification of the claimed microorganism is not possible using this certificate. For that reason, the rejection under 35 U.S.C. 112 first paragraph is maintained.

2. Applicants argue that R1 discloses a rotary disc process for preparing microspheres of freeze-dried microorganisms in a fatty acid matrix capable of maintaining bacterial activity in acidic environment. Further, they argue that R1 does not disclose a liquid food product with a pH of 4.5 or less.

a. The encapsulated microspheres disclosed by R1 have characteristics which overlap the characteristics of the presently claimed microspheres. The microspheres disclosed by R1 encapsulate Lactobacilli, their particle size is less than 250 microns, and have been encapsulated using stearic acid (saturated fatty acid). Therefore, R1 meets the requirements of the presently claimed invention.

Regarding the incorporation of such microspheres in foods, The Examiner has already acknowledged that R1 does not incorporate such microspheres in foods. However, the rejection is an obviousness type rejection and as the rejections indicate, R2 clearly teaches of incorporating encapsulated probiotics into foods such as yogurt.

3. Applicants arguer that R2 teaches of encapsulated bacteria using a mixture of hardened oil and starch and that the size of the capsules are larger than what is being claimed.

a. The encapsulation of lactic acid bacteria without using starch is disclosed by R1. In obviousness type rejections, all references are not require to disclose all the features of the claimed invention.

However, note that while R2 and R3 do not disclose all the features of the present claimed invention, R2 or R3 is used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention.

4. Applicants argue that R1 discloses encapsulated bacteria using very specific equipment.

a. The equipment or the processes involving encapsulation of bacteria are not the requirements of the presently claimed invention. Therefore, this argument has no objective. What is important is that the presently claimed invention is obvious considering the teachings of R1.

5. Applicants argue that R1 does not allow the skilled person to prepare granules of microorganisms which are small enough to be acceptable from an organoleptic point of view.

a. Please refer to the teachings of R1 for particle size of the encapsulated material. R1 discloses particles to be less than 250 microns. This range includes the presently claimed range of less than 200 microns.

6. Applicants remarks regarding the newly cited References (in their Information Disclosure Statement) have been considered.

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
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/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1781